



OCT 08 2002

K022322

GE Medical Systems

P.O. Box 414, W-709  
Milwaukee, WI 53201  
USA

### 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.  
Senior Regulatory Programs Manager  
GE Medical Systems  
Tel. ~~(414)~~ 544-3894  
Summary prepared: 5 June, 2002

Identification of Product(s): Innova 2000 and Innova 2000 S  
Classification Name: Solid State X-ray Imaging System  
Manufacturer: GE Medical Systems Europe  
283, rue de la Minière  
78530 Buc Cedex, France  
Distributed by: GE Medical Systems, Milwaukee, WI

Marketed Devices: The Digital Fluoroscopic Imaging Systems are substantially equivalent to the currently marketed cardiographic system **LCV+ Version 2** (K993037) that complies with the same or equivalent standards. -  
The optional Fast Spin rotational angiography feature in the Innova 2000 system is substantially equivalent to the LCA system (K945375) for this feature.

Device Description: The **Digital Fluoroscopic Imaging System** is designed to perform fluoroscopic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a Fiber Channel link to an acquisition equipment then to network (in using DICOM) for applications such as post-processing, printing, viewing and archiving. **Digital Fluoroscopic Imaging System** consists of an angiographic monoplane positioner, a table, an X-RAY system and a digital detector.  
The Innova 2000 S system is identical to the Innova 2000 system but without the optional features.

New optional features : The offset C-arm permits rotational cardiac angiography over a total 200° at variable speed from 20° to 40°/sec with Cranio/Caudal angulation.

The SuperFast Gantry (SFG) includes capacitive sensor technology and optimized collision avoidance software that permits an increase of pivot and C-arm speed of up to 20°/sec.

**Materials:** All construction and materials are compliant with UL 2601.

**Design:** There are hardware and software redundancies to prevent from single point failures that could cause unintended motion.

**Energy Source:** 480 VAC 50/60Hz.

Indications for Use: The **Digital Fluoroscopic Imaging Systems** are indicated for use in generating fluoroscopic images of human anatomy for diagnostic and interventional cardiac angiography, and optionally, rotational cardiac angiography procedures. It is intended to replace fluoroscopic images obtained through the image intensifier technology.

Comparison with predicate These systems are substantially equivalent to the Fluoroscopic system LCV+ Version 2 (K993037).  
The optional Fast Spin rotational angiography feature in the Innova 2000 system is substantially equivalent to the LCA system (K945375) for this feature.

Summary of Studies: Not applicable as the digital technology (SSXD, i.e., flat panel detectors) has already been clinically compared in the submission of LCV+ Version 2 (K993037) with the image intensified technology system LC introduced in 1989 (cleared under K890348) and found substantially equivalent.

Conclusions: GE considers the systems to be equivalent with the predicate devices. The systems provide fluoroscopic images that are equivalent to the diagnostic capabilities of the predicate device images. The potential hazards, e.g., wrong measurements, misdiagnosis and increased gantry speeds are controlled by a risk management plan including:

- A hazard identification
- A risk evaluation
- A Software Development and Validation Process



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Larry A. Kroger, Ph.D.  
Senior Regulatory Programs Manager  
GE Medical Systems  
P.O. Box 414  
MILWAUKEE WI 53201

Re: K022322  
Trade/Device Name: Innova 2000 and Innova 2000S  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified fluoroscopic  
x-ray system  
Regulatory Class: II  
Product Code: 90 MQB  
Dated: July 16, 2002  
Received: July 17, 2002

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

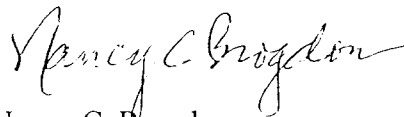
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K022322

Device Name: **Digital Fluoroscopic Imaging System – Innova 2000 and Innova 2000 S**

Indications for Use

The **Digital Fluoroscopic Imaging Systems** are indicated for use in diagnostic and interventional cardiac angiography and optionally, rotational cardiac angiography procedures of human anatomy. It is intended to replace image intensifier fluoroscopic systems in all diagnostic or interventional cardiac angiography procedures.

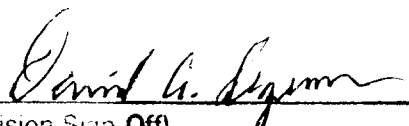
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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801-109)

OR Over-The-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K022322